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Anh Nguyen
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To: NCIC HPV@EPA
cc:
Subject: Environmental Defense comments on the Crude Oil category

----- Forwarded by Anh Nguyen/DC/USEPA/US on 04/15/2004 06:49 AM -----

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04/14/2004 03:41 PM

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Subject: Environmental Defense comments on the Crude Oil category

(Submitted via Internet 4/14/04 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, lucierg@msn.com and grayt@api.org)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for the Crude Oil category.

The test plan and robust summaries for the Crude Oil category were submitted by the American Petroleum Institute. The plan is well-written, informative and objective, and consistent with the spirit of right-to-know, which is a central goal of the HPV Challenge Program.

Although Crude Oil is termed a category for HPV purposes, this is really a complex mixture of varying composition depending on the source of the crude oil and other factors. Nevertheless, we support the designation of a category for different crude oil mixtures. Crude oil is used in a wide variety of applications and there is ample opportunity for environmental, worker and general population exposures to these complex mixtures.

The sponsor proposes to conduct a combined reproductive/developmental/ repeat dose toxicity study on two crude oil samples; one high in paraffinic compounds and the other high in aromatic compounds. Paraffinic crude oils are high in straight-chain and branched paraffins, while naphthenic crude oils are rich in naphthenic and aromatic hydrocarbons. This selection of test substances seems reasonable, and the proposed studies are warranted because there are limited data available on reproductive and developmental toxicity endpoints.

However, the dermal route of exposure is proposed for these studies and the sponsor claims that this is the most relevant route of exposure. We are concerned with this proposal, as no pharmacokinetic data were presented to support the notion that there is significant dermal absorption of the constituents of crude oil to be used in these studies; in addition, it appears likely that the oral or inhalation routes might also be relevant and perhaps even more significant than the dermal route. Therefore, we recommend that additional justification be provided prior to final selection of the route of exposure.

Other specific points are as follows:

1. Crude oil mixtures contain a wide array of toxicants, including polyaromatic hydrocarbons, benzene, arsenic, vanadium, nickel, hydrogen sulfide and many others. We recommend that the test substances used for the

repeat dose/reproductive/developmental toxicity studies be fully characterized by chemical analysis prior to dosing. This step is important for understanding potential differences in outcomes for the two test substances.

2. The robust summaries indicate that crude oil is not mutagenic, but concentrated extracts of crude oil are genotoxic. This is not surprising, as there are many mutagenic substances in crude oil. We suggest that the two test substances used in the mammalian toxicity studies be evaluated for in vitro mutagenicity, for the purpose of characterizing the test substances and facilitating comparison to previous studies using different crude oil mixtures.

3. The sponsor states that crude oil is harmful to aquatic organisms, and oil spills are cited to provide real-world data on the ways that crude oil can harm the environment. While considerable data are available on ecological toxicity, there is relatively little information on biodegradation. The sponsor proposes to address this endpoint through technical discussion, rather than proposing additional studies. Inasmuch as crude oil has been released into the environment, sometimes in huge amounts, we recommend that the sponsor conduct biodegradation studies on the two test samples and also generate data on the biodegradation of some of the more toxic constituents present in those samples.

4. Existing mammalian acute toxicity studies indicate that the liver, thymus and blood are the primary sites of toxicity, although acute toxicity is low. If data on the composition of test samples used in these studies are available, they should be presented along with the results of the existing and proposed studies.

Thank you for this opportunity to comment.

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